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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/558,871	04/28/2000	John F. Norris	P-8873	3151

27581 7590 01/31/2003

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EXAMINER	
DROESCH, KRISTEN L	
ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 01/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/558,871	Applicant(s) NORRIS ET AL. MP
	Examiner Kristen L Droesch	Art Unit 3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4-6, 9, 15-16, 19-21, 24, 31-34, 37, 43- 44, 47-49 and 52* is/are rejected.

7)☒ Claim(s) *3,7,8,10-14,17,18,22,23,25-30,35,36,38-42,45,46,50,51 and 53-58* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 April 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

1. Claim 10 is objected to because of the following informalities: it is missing a verb such as "evaluate" in the second clause. The examiner suggests " . . . and evaluates cardiac risk based on differences in the Fourier analysis . . ." or ". . . and cardiac risk is evaluated based on differences in the Fourier analysis . . ." Appropriate correction is required.

2. Claim 46 is objected to because of the following informalities: "evaluatingcardiac".

3. Claim 56 is objected to because of the following informalities: "evaluatingmeans"

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1, 2, 4-6, 9, 15-16, 20-21, 24, 31-34, 37, 43- 44, 48-49 and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Levine et al. (6,058,328).

With respect to claims 1, 16, and 44, Levine et al. shows an implantable medical device and method comprising a electrical cardiac activity sensor, and a T-wave analyzer that analyzes cardiac risk base on a comparison of the indication of T-wave alternans to a predetermined criterion (Col. 13, line 34-Col. 14, line 53, Col. 28, line 38-Col. 29, line 16, Col. 33, lines 42-61).

Regarding claims 2, and 31, Levine et al. shows a pacing generator that applies increased rate pacing stimuli (Col. 15, line 14-30).

With respect to claims 4 and 32, Levine et al. shows a memory (Col. 28, lines 55-59).

Regarding claims 5, 20, 33, and 48, Levine et al. shows providing an alert by initiating preemptive tachycardia pacing therapy.

Regarding claims 6, 21, 34, and 49, Levine et al. shows the T-wave analyzer analyzes differences in the QT interval over a series of two or more heartbeats to evaluate cardiac risk (Col. 33, lines 42-61).

With respect to claims 9, 24, 37 and 52, Levine et al. shows the T-wave analyzer analyzes differences in the T-wave characteristics (time of occurrence following Q wave) over a series of two or more heartbeats to evaluate cardiac risk (Col. 33, lines 42-61).

With respect to claims 15 and 43, Levine et al. shows a pacing generator that applies pacing stimuli and a processor or controller that controls the pacing generator based on the indication of T-wave alternans (Col. 13, line 34-Col. 14, line 53, Col. 15, line 14-30, Col. 28, line 38-Col. 29, line 16, Col. 33, lines 42-61).

6. The functional language and statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 19, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine et al. (6,058,328) in view of KenKnight (6,148,230). Although Levine et al. fails to show means for storing T-wave alternans indications provided by the sensor in a memory, attention is directed to KenKnight who shows a similar device that stores T-wave alternans indications (Col. 3, lines 45-52, Fig. 2, Col. 4, lines 1-15, 36-41). KenKnight teaches that the T-wave alternans information stored in the memory can be utilized to reprogram or modify the device via telemetry or the device may use the information to auto-learn over time. Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Levine et al. by adding the means for storing T-wave alternans indication provided by the sensor in a memory of KenKnight in order to utilize the T-wave alternans information stored in the memory to reprogram or modify the device via telemetry, or the device may use the stored information to auto-learn over time.

Allowable Subject Matter

9. Claims 3, 7-8, 10-14, 17-18, 22-23, 25-30, 35-36, 38-42, 45-46, 50-51, and 53-58 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. With respect to claims 3, 18, and 46, the prior art of record fails to teach or suggest a device and method including an implantable medical device that includes a T-wave analyzer, responsive to an electrical sensor, that evaluates cardiac risk based on a comparison of an indication of T-wave alternans to a predetermined criterion, in combination with a second sensor that senses increased heart rate and triggers to T-wave analyzer to evaluate cardiac risk.

11. Regarding claims 7, 22, 35, and 50, the prior art of record fails to teach or suggest a device and method including an implantable medical device that includes a T-wave analyzer, responsive to an electrical sensor, that evaluates cardiac risk based on a comparison of an indication of T-wave alternans to a predetermined criterion, in combination with the T-wave analyzer that analyzes differences in the amplitude of the T-wave over a series of two or more heartbeats.

12. With respect to claims 8, 23, 36, and 51, the prior art of record fails to teach or suggest a device and method including an implantable medical device that includes a T-wave analyzer, responsive to an electrical sensor, that evaluates cardiac risk based on a comparison of an indication of T-wave alternans to a predetermined criterion, in combination with the T-wave analyzer that analyzes differences in the slope of the T-wave over a series of two or more heartbeats.

13. Regarding claims 10, 25, 38, and 53, the prior art of record fails to teach or suggest a device and method including an implantable medical device that includes a T-wave analyzer, responsive to an electrical sensor, that evaluates cardiac risk based on a comparison of an indication of T-wave alternans to a predetermined criterion, in combination with the T-wave analyzer that evaluates cardiac risk based on differences in a Fourier analysis over a series of two or more heartbeats

14. With respect to claims 11, 26, 39, and 54, the prior art of record fails to teach or suggest a device and method including an implantable medical device that includes a T-wave analyzer, responsive to an electrical sensor, that evaluates cardiac risk based on a comparison of an indication of T-wave alternans to a predetermined criterion, in combination with the T-wave analyzer that compares alternate repolarization signals over a series of two or more heartbeats to evaluate cardiac risk.

15. Regarding claims 12, 27, 40, and 55, the prior art of record fails to teach or suggest a device and method including an implantable medical device that includes a T-wave analyzer, responsive to an electrical sensor, that evaluates cardiac risk based on a comparison of an indication of T-wave alternans to a predetermined criterion, in combination with the T-wave analyzer that counts the number of times the T-wave alternans satisfies the criterion and if the number exceeds a predetermined threshold indicating cardiac risk.

16. With respect to claims 13, 28, 41, and 56, the prior art of record fails to teach or suggest a device and method including an implantable medical device that includes a T-wave analyzer, responsive to an electrical sensor, that evaluates cardiac risk based on a comparison of an indication of T-wave alternans to a predetermined criterion, in combination with the T-wave

analyzer that analyzes a relationship between the T-wave alternans and the predetermined criterion over a period of time and stores the results of the analysis in the memory.

17. Regarding claims 14, 29, 42, 57, the prior art of record fails to teach or suggest a device and method including an implantable medical device that includes a T-wave analyzer, responsive to an electrical sensor, that evaluates cardiac risk based on a comparison of an indication of T-wave alternans to a predetermined criterion, in combination with a digital signal processor that analyzes T-wave morphology for evaluating cardiac risk.

18. With respect to claims 17, 30, 45, 58, the prior art of record fails to teach or suggest a device and method including an implantable medical device that includes a T-wave analyzer, responsive to an electrical sensor, that evaluates cardiac risk based on a comparison of an indication of T-wave alternans to a predetermined criterion, in combination with a pacing generator that applies an increased pacing rate to facilitate sensing of the T-wave alternans.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Callaghan (5,271,393) shows a device that integrates the QT interval and compares it with a predetermined threshold indicating dispersion of repolarization and an imminent tachyarrhythmia. Verrier et al. (5,842,997) shows a non-invasive means for monitoring T-wave alternans utilizing complex demodulation, estimation by subtraction, least squares estimation and auto-regressive algorithms. Verrier evaluates risk for sudden cardiac death by monitoring the combination of T-wave alternans with heart rate variability and QT interval dispersion. Zehender (5,497,780) shows an implantable device that analyzes the morphology of the T-wave in evaluating ischemia. Lander (5,827,195) and Nearing et al. (6,169,919) both show non-

invasive devices that quantify T-wave alternans utilizing a comparison of even numbered T-waves to odd T-waves.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 8:00 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Kristen Droesch

kld
January 24, 2003

KENNEDY J. SCHAETZLE
PRIMARY EXAMINER
1-24-03